Classification Discussion: Mechanical Wheelchairs

21 CFR 890.3850

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Outline

1. Device Description
2. Regulatory Background
3. Clinical Evidence
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    - Adverse Event Information from MAUDE
    - Recall Information
4. FDA classification recommendation
    - Risks to Health
    - Safety and Effectiveness
    - Special Controls

Purpose of Meeting

Currently: Mechanical wheelchairs are Class I (reserved) and require a 510(k) for marketing clearance

Proposed: Reclassify to Class II (special controls) and exempt from 510(k)

- General controls alone are insufficient to provide reasonable assurance of safety and effectiveness
- Sufficient information to generate special controls that in addition to general controls may be used to provide reasonable assurance of safety and effectiveness

Obtaining input regarding reclassification from the panel in preparation of a proposed order.

Device Description

- Indicated to transport individuals restricted to a sitting position
- Fundamental design of seat (where user is located) and use of multiple wheels concept remains relatively unchanged from pre-amendment devices
- Updated materials, safety testing, mechanical testing, etc…
- Device allows user to ambulate over terrain
- Labeling should state limitations to user (weight limitations, tipping angle, curb height, safe recline-if available)

Device Description

Common features, components, and accessories include:

- Suspension for Frame
- Handrims/Pushrims
- Wheel Locks
- Grade-Aids
- Attendant Handles
- Adjustable Dimensions (length, width, depth)
- Tilt-in-Space
- Footrest/Armrest

Regulatory Background

Wheelchair Regulations

Class III	890.3890 – Stair-climbing wheelchair
Class II (510(k))	890.3860 – Powered wheelchair 890.3880 – Special grade wheelchair 890.3900 – Standup wheelchair
Class I (reserved) (requires 510(k))	**890.3850 – Mechanical wheelchair**
Class I (exempt from 510(k))	890.3910 – Wheelchair accessory 890.3920 – Wheelchair component

Mechanical Wheelchair

21 CFR 890.3850 – Mechanical wheelchair

- *Identification*. A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

- *Classification*. Class I (General Controls)
- Require pre-market notification (510(k))

Regulatory History – 1976-1979

- In 1979 meeting of Physical Medicine Device Classification Panel, discussed request to exempt mechanical wheelchairs from the requirements of premarket notification records and reports and CGMP (Current Good Manufacturing Practice) regulations

- FDA stated "*compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness and compliance with the adulteration and misbranding provisions of the act. Compliance with the CGMP regulations will help prevent production of a mechanical wheelchair having defects that could harm users.*" (48 FR 53032)

Regulatory History –1997

- In 1997, determined to be of substantial importance in preventing impairment of human health or a device that presents a potential unreasonable risk of illness or injury (Section 206(2) of Food and Drug Modernization Act (FDAMA))
- These devices were determined to not be exempt from premarket review & subject to submission of 510(k)

Current Regulatory Pathway

- The earliest mechanical wheelchair devices relied on comparison to “pre-amendments” devices (on the market prior to 1976)

- 385 total 510(k) submissions cleared

Clinical Evidence

- Literature Review
- MDR (Medical Device Reports)
- Recalls
- Summary of Available Evidence

Literature Review

- Background
- Methods
- Findings on safety of mechanical wheelchairs

A systematic literature review of mechanical wheelchairs was performed to address what adverse events are associated with these devices.

Literature Review - Methods

- Searched PubMed using the following terms:
  - Mechanical wheelchair
  - Manual wheelchair
- Limited literature review to:
  - Human studies
  - Published in English
- Yielded 1,362 unique hits
- Narrowed search by “safety”, “risk”, “injury” or “injuries”
- Yielded 106 unique hits

Literature Review - Methods

106 studies identified and further narrowed by eliminating studies related to the following:

- User skills assessment
- Safety of device while used/transported in motor vehicle
- Articles related to components
- Articles related to repeated shoulder stress from propulsion

Literature Search

23 studies Identified for in-depth review

- Studies of reported adverse events or adverse events captured (7)
- Studies and analyses of pressure ulcers and deep tissue injury (9)
- Bench testing comparison of wheelchairs (7)

Literature - Adverse Events

1. **Calder et al (1990) – Search of death certificates from 1973-1987**

- 770 cases of deaths (includes mechanical and powered wheelchairs)
- Death was related to falls for 596 users
- Most often reported injuries: fracture (n=512), respiratory disorder (397), subdural hemorrhage (83) and cerebral contusion (65)

Literature - Adverse Events

2. Ummat et al (1994) – Search of National Electronic Injury Surveillance System (NEISS) between 1986-1990

- 2066 cases (includes mechanical and powered wheelchairs)
- Major causes of accidents were falls and tips (73.2% of cases)
- Other reported causes (41.4%) were furniture, stairs, toilets, bathrooms and ramps
- Fractures most common among fatal accidents (62.5% of fatal accidents)
- Most common non-fatal accidents were: contusions, abrasions and lacerations

Literature - Reported Adverse Events

3. Kirby et al (1995) – Reportable events submitted to FDA between August 1975 through October 1993

- 22.6% of 627 records attributable to mechanical wheelchairs
- Fractures most common (N=143)
- Laceration (70)
- Contusions/abrasions (63)
- Concussions/subdural hematoma (9)
- Dislocation (5)
- Dental injury (4)
- Puncture (4)
- Strain/sprain (4)
- Burns, thermal (4)

Literature - Adverse Events

4. **McClure et al (2009) – 16 facilities form national Model Spinal Cord Injury System facilities (MSCIS) asked how often wheelchairs (mechanical and powered) were repaired**

- April 2004 through March 2006
- 1,364 of 2,213 had a mechanical wheelchair
- 497 participants completed a major repair on mechanical wheelchair
- 24 full-time mechanical wheelchair users injured

Literature - Adverse Events

5. **Worobey et al (2012) – Survey of 723 mechanical and powered wheelchair users**

- 52.6% of full-time wheelchair users experienced major repair in past 6 months
- No reported injuries as a result of breakdowns

Literature - Adverse Events

6. Gaal et al (2007) – Interview of 109 Riders

- 253 incidents (47% which occurred in mechanical wheelchairs)
- Tips and falls (66)
- Component failures (27) including: caster (12), frame (7), rear axle & tire (6), footrest (2) and miscellaneous (1)
- Other events (25): hit immovable object (17), van/bus lift (3), transport in vehicle (2), injury contact with chair (2) and hit by a car (1)

Literature - Adverse Events

7. **Chen et al (2011) – Survey of 95 participants (mechanical and powered) over 3 year period**

- Categorized: tips and falls, accidental contact and dangerous operation
- 52 users reported at least one incident & 16 reported two or more incidents
- 49 of 50 for mechanical wheelchairs were reported as tips and falls, and one as accidental contact
- Most common abrasion/laceration (29), followed by sprain or contusion, head injury, fracture and organ injury

Literature - Deep Tissue Injury

Studied patient factors associated with sore formation including:

- Seated pressure
- Seated incline
- Seat cushion design
- Patient obesity
- Did not address incidence of pressure sores but did evaluate biomechanics of patient interfaces to help determine risk of pressure sore formation

8. Agam et al. (2008), 9. Elsner et al. (2008), 10. Giesbrecht et al. (2011), 11. Gil-Agudo et al. (2009), 12. Linder-Ganz et al. (2009), 13. Maurer et al. (2004), 14. Portnoy et al. (2011), 15. Taule et al. (2013), 16. Mak et al. (2010)

Literature - Bench Testing

- Used test dummies (no adverse events)
- Evaluated characteristics and factors related to user safety
- Variability in performance characteristics

Indicates necessity of performance standards to provide assurance of minimal level of performance

17. Kirby et al. (1996), 18. Cooper et al. (1999), 19. Cooper et al. (1996), 20. Cooper et al. (1997), 21. Kwarciak et al. (2005), 22. Liu et al. (2008), 23. Liu et al. (2010)

MAUDE

- MAUDE (Manufacturer and User Facility Device Experience) maintained by Office of Surveillance and Biometrics (OSB) at FDA
- Fully implemented in 1996
- Adverse event reports can be submitted by manufacturers, user facilities, importers and voluntary reports
- Medical device manufacturers required to report adverse events
- Not all events are captured since this is a voluntary reporting system

MAUDE

- Searched adverse event reports from January 1, 2006 through September 13, 2013 for “mechanical” AND “wheelchair” OR “manual” AND “wheelchair”

MAUDE Search Results

- Total of (3,492) adverse events related to mechanical wheelchairs reported
- (7) deaths
- (265) injuries
- (3,209) malfunctions
- Remaining (10) were categorized as “other.”

MAUDE Search Results - Deaths

The device concerns associated with the death reports were:

- (1) attributed to device-Detachment of hand grips, resulting in fall with multiple injuries
- (4) attributed to use error
- (2) unknown cause in which device cannot be ruled out

- Use error included: failure to set brakes (2), tip-over while turning around in bathroom (2), fall forward while restrained (1) and fall backward (1)
- Unknown cause included: head trauma/subdural hematoma (2), restraint strangulation (1) and injuries from van accident (1)

MAUDE Search Results - Injuries

265 serious injury reports

- 110 attributed to device
- 44 attributed to use error
- 111 unknown cause where device cannot be ruled out

MAUDE Search Results - Injuries

Most common reported patient injuries are:

- Fractures (98)
- Falls (54)
- Amputation of finger tip (32)
- Cuts or lacerations (29)
- Head injuries (14)
- Pressure sores (7)
- Unspecified injury (7)
- Teeth knocked out (4)
- Injuries to knee and wrist (2)
- Back injury (1)
- Nerve damage (1)

MAUDE Search Results - Malfunctions

- 3,209 malfunction reports
- 317 total reports for analysis
- Most common malfunctions related to following components:

- Frame break
- Wheel locks/brakes
- Cross brace
- Wheels/castors
- Frame/back rest
- Handle/grips
- Tires
- Wheel spokes
- Arm rest
- Tilt/recline
- Seat upholstery
- Foot rest plate
- Leg/foot rest
- Plastic seat guides

Recalls

- There were a total of 12 recalls from 7 firms from January 1, 2006 until September 13, 2013
- All recalls were class 2, which is defined as “a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote”

Recalls

Recalls were due to failures of components which included:

- Anti-tippers
- Tie-down brackets
- Folding mechanism
- Handles
- Stabilizer bar
- Backrest/back support assembly
- Armrests
- Wheels

Available Evidence

- Identified several risks associated with mechanical wheelchairs
- Most frequently reported injuries are falls and fractures
- Adverse event information identified in MAUDE encompasses risks identified in literature
- The literature, MDRs, and recall information do show that these devices can be prone to component breaks or failures

Classification Recommendation

Classification Definitions (Class III)

FD&C Act-Section 513-Title 360(c)(a)(1)(C): A device is in Class III if…

- Cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device **AND**
- Cannot be classified as a class II device because insufficient information exists to determine that special controls would provide reasonable of safety and effectiveness **AND**
  - Is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health **OR**
  - Presents a potential unreasonable risk of illness or injury

Classification Definitions (Class II)

FD&C Act-Section 513-Title 360(c)(a)(1)(B): A device is in Class II if…

- Because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device **AND**
- For which there is sufficient information to establish special controls to provide such assurance.

Examples of special controls include: performance standards, postmarket surveillance, patient registries, special labeling requirements, and development and dissemination of guidelines

Classification Definitions (Class I)

FD&C Act-Section 513-Title 360(c)(a)(1)(A): A device is in Class I if…

- General controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device **OR**
  - Is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, **AND**
  - Does not present a potential unreasonable risk or illness or injury.

Risks to Health

FDA has identified the following risks:

- Instability
- Entrapment
- Use Error
- Falls/Fractures
- Pressure sores
- Burns

Panel Question

The panel will be asked to comment on whether you believe FDA has identified a complete and accurate list of the risks to health presented by mechanical wheelchair devices.

The panel will be asked if they disagree with inclusion of any of these risks or whether they believe any other risk should be included in the overall risk assessment of mechanical wheelchair devices.

Reasonable Assurance of Safety

- There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probably risks.
- The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

[21 CFR 860.7(d)(1)]

Reasonable Assurance of Effectiveness

There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

[21 CFR 860.7(e)(1)]

FDA Assessment Safety and Effectiveness

- Identified several risks associated with mechanical wheelchairs
- Most frequently reported injuries are falls and fractures
- Adverse event information identified in MAUDE encompasses risks identified in literature
- The literature, adverse events, and recall information do show that these devices can be prone to repair and component breaks or failures

The panel will be asked to comment on whether, based on the available scientific evidence, there is a reasonable assurance of safety and effectiveness for mechanical wheelchair devices when intended to provide mobility to persons restricted to a sitting position.

Special Controls

If the Panel were to recommend a Class II determination, FDA recommends special controls should include the following:

- The design characteristics of the device must ensure that the geometry and materials composition are consistent with the intended use
- The skin-contacting components of the device must be demonstrated to be biocompatible
- Performance testing must evaluate the flammability of device components
- Patient and clinician labeling

Special Controls

- Performance testing must demonstrate adequate mechanical performance under simulated use conditions and environments. Performance testing must include the following:
  - Fatigue testing
  - Endurance testing
  - Resistance to dynamic loads (impact testing)
  - Demonstration of adequate stability of the device on inclined planes (forward, backward and lateral)

Panel Question

The panel will be asked to discuss the adequacy of these proposed special controls to ensure a reasonable assurance of safety and effectiveness in light of the available scientific evidence.

The panel will be asked whether special controls mitigate the risks to health for mechanical wheelchair devices and provide a reasonable assurance of safety and effectiveness in light of the available scientific evidence.

Classification

- For mechanical wheelchairs, FDA believes that the available evidence suggests that special controls can be used to provide a reasonable assurance of safety and effectiveness
- Special controls can be defined to address safety
- FDA believes that with establishment of special controls, clearance of 510(k) is not necessary to ensure reasonable assurance of safety and effectiveness
- ***Based on the available scientific evidence and proposed special controls, the Panel will be asked whether maintaining the current classification and regulatory status or reclassifying to Class II (general controls and special controls) is appropriate for mechanical wheelchairs "for individuals who have mobility impairments and require and assistive device for mobility."***

Thank you!